

We claim:

1. A topical lotion comprising:

about 0.005 to 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof;

about 1.0 to 10.0 wt.% of a C₁₄-C₂₀ fatty alcohol or mixtures thereof;

about 1.0 to 5.0 wt.% of at least one skin conditioning agent;

about 5.0 to 15.0 wt.% propylene glycol;

up to about 10.0 wt.% miheral oil or white soft paraffin; and the balance in water.

2. A topical lotion comprising:

about 0.005 to 1.0 wt.% fluticasone propionate;

about 3.0 to 7.0 wt.% of a Q_{14} - Q_{20} fatty alcohol, or mixtures thereof;

about 0.5 to 3.0 wt.% of at least one skin conditioning agent;

about 0.25 to 2.0 wt.% of at least one surfactant;

about 7.0 to 12.0 wt.% propylene glycol;

up to about 10 wt.% of mineral oil or white soft paraffin; and

the balance in water.

- 3. The lotion according to claim 1, further comprising less than about 5.0 wt.% dimethicone.
- 4. The lotion according to claim 2, further comprising less than about 5.0 wt.% 25 dimethicone.
 - 5. The lotion according to claim 1, wherein said pharmaceutically acceptable ester of fluticasone is fluticasone propionate.
- 30 6. The lotion according to claim 1, comprising:

about 0.05 wt.% fluticasone propionate,

about 5.0 wt.% cetostearyl alcohol,

about 1.0 wt.% isopropyl myristate,

about 1.0 wt.% dimethicone,

35 about 1.0 wt.% cetomacrogol,

20

5

Subbital Corital

about 10.0 wt.% propylene glycol less than about 0.30 wt.% imidurea, less than about 0.20 wt.% methyl paraben, less than about 0.10 wt.% propyl paraben, about 0.05 wt.% citric acid (anhydrous), about 0.08 wt.% sodium citrate, and the balance in purified water.

=20

7. The lotion according to claim 1, comprising: about 0.05 wt.% fluticasone propionate, about 5.25 wt.% cetostearyl alcohol, about 2.0 wt.% isopropyl myristate, about 10.0 wt.% propylene glycol, about 0.20 wt.% imidurea, about 0.20 wt.% methyl paraben, about 0.10 wt.% propyl paraben, and the balance in purified water.

8. The lotion according to claim 1, having a viscosity of about 2,000 to 17,000 cps as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C.

July 25

30

- 9. The lotion according to claim 2, having the formula about 5.25 wt.% cetostearyl alcohol, about 2.0 wt.% isopropyl myristate, about 10.0 wt.% propylene glycol, about 0.20 wt.% imidurea, about 0.20 wt.% methyl paraben, about 0.10 wt.% propyl paraben, and the balance in purified water.
- 10. The lotion according to claim 1, having a viscosity of from about 3,000 to 13,000 cps as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C

25

30



- 11. The lotion according to claim 2, having a viscosity of from about 3,000 to 13,000 cps as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C.
- 5 12. The lotion according to claim 1, free of mineral oil or white soft paraffin.
 - 13. The lotion according to claim 2, free of mineral oil or white soft paraffin.
 - 14. Use of the lotion according to claim 1 to increase the vasoconstrictor potency of fluticasone.
 - 15. Use of the lotion according to claim 2 to increase the vasoconstrictor potency of fluticasone proprionate.
 - 16. A process for preparing a lotion according to claim 1, comprising: mixing the ingredients recited in claim 1 at an elevated temperature; and cooling said mixture.
 - 17. A process for preparing a lotion according to claim 1, comprising: mixing the ingredients recited in claim 1 at an elevated temperature; and heating said mixture.
 - 18. A topical lotion comprising:
 about 0.005 to about 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof;
 - a thickening effective concentration of at least one thickener; a conditioning effective concentration of at least one skin conditioning agent; an emulsifying effective amount of a surfactant, and the balance in water.
 - 19. The lotion of claim 18, wherein the lotion has a 2-hour mean blanching score of at least about 2.1, an AUC of at least about 26.7, and an average mean blanching of at least about 1.5.

500/

20. The lotion of claim 18, wherein the lotion is chemically and physically stable for at least 6 months at 40°C.

bub B

21. A method of treating a skin condition comprising: providing a lotion including about 0.005 to about 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof; about 1.0 to about 10.0 wt.% of a C_{14} - C_{20} fatty alcohol or mixtures thereof; about 1.0 to about 5.0 wt.% of at least one skin conditioning agents; about 5.0 to about 15.0 wt.% of propylene glycol; less than about 10.0 wt.% of mineral oil or white soft paraffin, and the balance in water; and, applying the lotion to the skin having the skin condition.

- 22. The method of claim 21, wherein the skin condition is corticosteroid-responsive dermatosis, atopic dermatitis, inflammation, eczema, erythema, papulation, scaling, erosion, oozing, crusting or pruritis.
- 23. The topical lotion of claim 21, wherein the lotion has a 2-hour mean blanching score of at least about 2.1, an AUC of at least about 26.7, and an average mean blanching of at least about 1.5.
- 24. The lotion of claim 21, wherein the lotion is chemically and physically stable for at least 6 months at 40°C.

